UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,976	07/27/2001	Jyoti Mazumder	POM-12602/29	8577

25006 7590 04/26/2007

GIFFORD, KRASS, SPRINKLE,ANDERSON & CITKOWSKI, P.C
PO BOX 7021
TROY, MI 48007-7021

EXAMINER	
KOSOWSKI, ALEXANDER J	
ART UNIT	**PAPER NUMBER**
2125	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/916,976
Filing Date: July 27, 2001
Appellant(s): MAZUMDER ET AL.

John G. Posa
Reg. No 37,424
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/2/07 appealing from the Office action mailed 9/6/06

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,405,095	Jang et al	06-2002
6,122,564	Koch et al	09-2000

US PGPUB 2002/0007294 (Bradbury et al) Published 01-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

2) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3) Claims 1 and 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang et al (U.S. Pat 6,405,095), further in view of Bradbury et al (U.S. PGPUB 2002/0007294), further in view of Koch (U.S. Pat 6,122,564).

Referring to claim 1, Jang teaches a method of fabrication comprising the steps of: receiving digital data from computer tomography or magnetic resonance imaging (col. 15 lines 6-10), constructing a computer-aided design (CAD) file in accordance with the digital data (col. 14 lines 28-62); generating a tool path (col. 15 line 48 though col. 16 line 30); and fabricating a

three-dimensional object by depositing material increments along the tool path using a closed-loop direct metal deposition (DMD) process of the type wherein a laser beam is focused onto a workpiece to create a melt pool into which powder is injected (col. 5 line 51 through col. 6 line 8 and col. 16 lines 10-16). However, Jang does not explicitly teach that biomedical implants are being fabricated, that the digital data obtained from CT or MRI scans is related to patient physiology, nor that the size of the increments are controlled through optical monitoring.

Bradbury teaches a system for rapidly prototyping biomedical implants whereby CAD models are created after patient-specific anatomical digital data is gathered, and whereby data is converted to manufacturing instructions comprising tools paths to create three-dimensional models (Paragraphs 0007, 0016 and 0022).

Koch teaches a method of fabrication utilizing DMD techniques including a melt pool (col. 3 lines 52-53 and col. 5 lines 32-33), whereby an optical monitoring system is utilized as feedback to control the size of deposited material increments (col. 5 lines 54-65).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to receive digital data representative of patient physiology and to fabricate biomedical implants using the method taught by Jang since this would increase the responsiveness of the implant preparation and surgical planning process, would allow customized construction of implants, and would yield superior dimensional matching to a patient's body, which should promote superior tissue and bone ingrowth (Bradbury, Paragraphs 0008 and 0051).

It would also have been obvious to one skilled in the art at the time the invention was made to utilize optical monitoring to control the size of deposited material increments in the method taught by Jang above since optical detection means can be utilized to monitor physical

dimensions of deposits, and a feedback controller can utilize this to adjust a laser to thereby control the rate of material deposition (Koch, col. 2 lines 5-9).

Referring to claim 3, Jang teaches the method of claim 1, wherein the materials include one or more metals or ceramics (col. 5 lines 51-58).

Referring to claim 4, Jang teaches the method of claim 1, wherein the materials may include alumina (col. 5 lines 3-6).

Referring to claim 5, Jang teaches the method of claim 1, further including the step of fabricating the object out of different materials using the same DMD process (col. 6 lines 3-8).

Referring to claim 6, Jang teaches the method of claim 5, wherein the different materials include metals, ceramics, or polymers (col. 5 line 51 through col. 6 line 8).

Referring to claim 7, Jang teaches the above. However, Jang does not explicitly teach the step of embedding one or more sensors into the implant for diagnostic or data-acquisition purposes.

Bradbury teaches that sensors may be seeded into implants for diagnostic purposes (Paragraph 0031).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to embed sensors in implants in the method taught above since this would allow a part to be inspected at a later point after fabrication (Bradbury, Paragraph 0031).

Referring to claim 8, Jang teaches the above. However, Jang does not explicitly teach fabricating a scaffold structure suitable to bone ingrowth or ongrowth using the DMD process.

Bradbury teaches fabricating scaffold structures of custom shapes to help bone ingrowth (Paragraphs 0051 and 0082-0083).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to fabricate scaffold structures in the method taught above since this would allow superior dimensional matching to a patient's body which would promote healing (Bradbury, Paragraph 0051).

(10) Response to Argument

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues with reference to claim 1 that the "paragraphs of Bradbury cited...refers only to the system of Bradbury...It does not speak to the combination...Thus, the teachings of this paragraph do not carry over beyond the application in which it is contained." In response, examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Bradbury reference specifically teaches motivations for adding the missing features of claim 1 into the Jang reference. The examiner has established in the rejection above that the claim limitations can be found in each reference, and that there is a motivation to combine found in the secondary references. Therefore, the requirements for an obviousness rejection under 35 U.S.C. 103(a) have been met.

In addition, Examiner notes that applicant appears to be addressing the references individually, rather than as a valid combination under 35 U.S.C. 103(a). Examiner notes that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that there is "no factual evidence...in support of Examiner's rationale for rejection...how does examiner know this?...there appears to be no reason or justification for the proposed combination...the remarks by Bradbury have only to do with Bradbury, and do not provide factual evidence for the proposed combination." In response, Examiner notes the response above. In addition, examiner notes Paragraphs 0008 and 0051 of Bradbury, which are cited for the motivation, recite the following:

[0008] The present invention ***significantly increases the responsiveness of the implant preparation and surgical planning process as well as allowing customized construction of the implant.*** *In accordance with the present invention, it is possible to transmit data back and forth, individually design and dimension an implant, visualize and confirm its suitability, manufacture it, deliver the implant to the doctor and implant it in a patient, all within a few days, which is much faster than presently possible. This would greatly increase the responsiveness of the medical system, with attendant benefits to patient treatment, especially in emergency treatment. It would also reduce geographical restrictions on the availability of this medical technology.*

[0051] The method just described provides a method of manufacturing biomedical devices such as ***implants that yield at least superior dimensional matching to the patient's body and hence should promote superior tissue and bone ingrowth*** *as compared to conventional methods. In general, the smaller the gap between fragments or surfaces which are intended to heal to each other, the greater the likelihood of successful healing is believed to be. The implants of the present invention are anatomically accurate, thus providing an optimal fit with the patient's anatomy, which should promote healing. Furthermore, internal microarchitectures can be designed into the implant to promote, guide, or discourage ingrowth of bone or other tissue in specific places. The configuration of the architecture provides an environment beneficial to and optimized to cell ingrowth, and further can be designed to create a unique cell-surface interface that facilitates rapid and specific cell migration into the implant. This is possible due to*

specifically designed architecture as well as the ability to place drugs, gene fragments, comb polymers, and growth factors in specific locations within the implant. Such details are included in the machine instruction file as just described. Using the machine instruction file, the device is manufactured such as by three-dimensional printing. It is then inspected, sterilized if required, packaged, and delivered to the user. (emphasis added)

As can be seen, the given motivation is known by the examiner because it comes directly out of the Bradbury reference. The motivation given by Bradbury relates directly to the claim limitations that the Bradbury reference is utilized to teach in the 35 U.S.C. 103(a) rejection given above.

Applicant argues that with regard to optical monitoring "there is no teaching or suggestion from the prior art in support of the proposed combination with respect to applicants claims, which are formulated in combination". Examiner disagrees, and notes the rejection of claim 1 above whereby specific motivation for the use of optical monitoring is cited directly from the Koch reference. The cited portion, namely col. 2 lines 5-9 of Koch, is submitted below.

Optical detection means coupled to an optoelectric sensor are used to ***monitor a physical dimension of the deposit, and a feedback controller is operative to adjust the laser in accordance with the electrical signal, thereby controlling the rate of material deposition.*** (emphasis added)

Therefore, applicants argument that there is no teaching from the prior art is not justified, as the teaching utilized by the examiner for motivation clearly comes directly from the prior art as evidenced above.

Finally, applicant argues again that "the examiner's other conclusions are as well unfounded" and that references to modifying Jang are "specific to the teachings of Bradbury, and

do not carry over to the proposed combination". In response, Examiner again references the response above, and notes that all rejections given under 35 U.S.C. 103(a) in the present office action satisfy the requirements of obvious combinations under 35 U.S.C. 103(a).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Alexander Kosowski

Conferees:

Leo Picard

Eddie Lee

LEO PICARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100

EDDIE C. LEE
SUPERVISORY PATENT EXAMINER